7T Surgery and Implant Safe List



General Note on 7T

- There are many more exclusions for what can be safely scanned at 7T compared to 3T
- Implants and surgeries that fall under 'Further Information Required' are likely to be excluded for 7T.
- The overriding concern, even with apparently trivial surgery, is the use of surgical clips, which while safe at 3T, pose a safety hazard at 7T.

Important Information

- Under no circumstances should this list be given to volunteers.
- This safety information is only applicable for the FMRIB Siemens Magnetom 7T.
- Without the risk versus benefit analysis that exists for clinical MRI, we must be much more cautious in a research environment.
- Therefore a volunteer that is excluded from having an MRI at FMRIB will, in many cases, be able to undergo a clinical MRI examination at a lesser field strength.

Screening

- It is a requirement that you go through the 7T Volunteer Screening Form at the initial recruitment stage.
- Any 'yes' responses that are not covered by this list must be checked with the radiographers via MRIsafety@fmrib.ox.ac.uk

Using The List

• Anything NOT on this list must be treated as 'Further Information Required'.

Using MRIsafety@fmrib.ox.ac.uk

- Any safety queries that are not covered in the list, are classified as 'Further Information Required' or as 'Likely Exclusion', should be directed to MRIsafety@fmrib.ox.ac.uk
- This is a ticketed system and your email will receive a reply with a reference number for the volunteer. Please reply to this acknowledgment email if you wish to add further information.
- Your email should
 - Relate to 1 volunteer only. If you have more than one volunteer with a safety query, each volunteer must have a separate email.
 - The subject line must contain the FMRIB study number, field strength, the volunteers DOB and gender, e.g. '2013 51 (7T) 01/01/1980 M'
 - Please include as much information in the body of the email as possible e.g. the procedure/s, reason for surgery, the hospital and country of surgery if not the UK, the manufacturer, model name or number of any implants used.
 - If you are including supporting documentation eg hospital notes, all identifying information other than DOB must be redacted.
- The radiographers will then investigate the MRI compatibility of the surgery or implant.
- Please note that manufacturers can take several weeks to provide compatibility information.
- If scanning is approved you must bring a print off of this email to the scanning session.

High Value Volunteers

- In exceptional cases it may still be possible to scan a high value volunteer that has an implant.
- Examples include where manufacturer safety information either doesn't exist or contraindicates scanning, or implant information cannot be obtained.
- Applications to scan such volunteers need to demonstrate that their exclusion will have a significant detrimental effect on the study.
- If an application is accepted, an implant risk assessment will be carried out along with an examination of any ethical and legal considerations.

X-raying Volunteers

- The use of ionising radiation in a research protocol requires REC approval under the Ionising Radiation (Medical Exposure) Regulations 2002 ("IRMER").
- Therefore you cannot x-ray a potential volunteer to check for clips or foreign bodies without explicit ethical approval.
- If this applies to your study please contact <u>MRIsafety@fmrib.ox.ac.uk</u> for details on how to organise an X-ray.

Surgery in the last 6 weeks



- As a general rule, a minimum of 6 weeks must have passed between any surgery and scanning
- This also includes diagnostic investigations such as laparoscopy and arthroscopy
- There are very few implants that have been tested at 7T and for those that have, they will usually require a period of time for scar tissue to firmly embed them into place
- Other considerations here include whether the volunteer will be able to lie comfortably for the scan and whether they fulfil the study's definition of a "healthy volunteer"

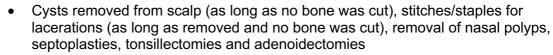
Endoscopy in the last 6 weeks



- With very few exceptions, 6 weeks must have passed between endoscopy and scanning.
- Some routinely used marking/tagging clips are highly ferrous (the volunteer may not be aware of their use)
- Endoscopy performed via pill camera is becoming more common place
- Both of these could result in serious injury if exposed to a strong magnetic field

Head and Brain Surgery/Implants

Safe





Further Information Required

- In general any volunteer with a history of brain surgery, including burr holes or biopsies, will be excluded from scanning (the risk comes from clips that may have been used during the surgery and not recorded)
- Other aspects that need to be considered include the presence of any implants including, but not limited to, cranial fixation devices, shunts (fixed or programmable), clips on sensitive structures, stents, coils

Likely Exclusion

Volunteers with aneurysm clips, neurostimulators

Eye Surgery/Implants

Safe

 Squint correction during childhood, laser eye surgery for vision correction, cataract surgery post 2000



Further Information Required

- All other eye operations including, but not limited to, squint correction as an adult, minor cosmetic surgery for a detached retina, lens implants not associated with cataract surgery, cataract surgery pre 2000
- All eye implants eg eye prostheses, metal weights in eyelids, eye lid springs

Likely Exclusion

Any volunteers with a history of a metallic penetrating eye injury where there is no radiological evidence of it being removed (even if removed medically)

Ear Surgery/Implants

Safe



 Grommets (regardless of when they were implanted or whether they are still present), cosmetic ear procedures eg pinoplasy

Further Information Required

 All other ear surgeries eg stapedectomies, stapedotomies, surgery for a ruptured ear drum

Likely Exclusion

• Volunteers with cochlear implants

Thoracic Surgery/Implants



Safe

Breast biopsy

Further Information Required

• Lumpectomies, mastectomies, lobectomies, breast implants, tissue expanders

Heart Surgery/Implants

Safe



Diagnostic angiography of coronary vessels

Further Information Required

 Coronary bypasses (including sternal wiring), coronary stents, PFO closure devices, artificial heart valves, if there is any history of a pacemaker or defibrillator that has now been removed (pacing wires aren't always removed)

Likely Exclusion

Pacemakers, defibrillators

Abdominal and Pelvis Surgery/Implants

Safe

Endoscopies (after 6 weeks)



Further Information Required

- Haemorrhoidectomies, haemorrhoid banding, appendectomies, cholecystectomies, sterilisations, vasectomies, C-sections, most gynaecological procedures, hysterectomies, prostate surgery
- Hernia repairs involving mesh, filters, stents, implanted drug delivery devices, colostomies, cystoscopies, pessaries, insulin or infusion pumps, implanted drug infusion devices, urinary catheters, penile implants, brachytherapy implants

Likely Exclusion

• Capsule endoscopy devices eg pill cam (until they have passed)

Spine Surgery/Implants

Safe



Lumbar puncture, facet joint injections

Further Information Required

- Any other surgeries including, but not limited to, discectomies, microdiscectomies, decompressions, laminectomies
- Spinal fusions, Anterior Cervical Discectomies and Fusions (ACDFs)

Likely Exclusion

Harrington rods, spinal cord stimulators

Contraceptive Implants



Safe

- The Mirena IUS & Jaydess IUS are safe provided they are outside of the transmit volume of the coil eg as is the case with studies using the 32-channel TxRx head coil
- Nexplanon and Implanon contraceptive implants

Further Information Required

• All other IUDs, contraceptive coils and diaphragms

Orthopaedic Surgery/Implants

Safe

Diagnostic arthroscopies



Further Information Required

- Any other surgery, even if the volunteer denies the presence of any implanted devices or clips
- Open reduction internal fixations (ORIFs) followed by removal of metallic implants (often removal can be incomplete)

Likely Exclusion

All joint replacements, ORIFS, bone/joint pins, screws, nails, wires, plates, etc

Vessel Surgery/Implants



Safe

Diagnostic angiography

Further Information Required

- Varicose veins (clips may be used), vessel grafts
- Stents, filters, vascular access ports and/or catheters

Dental Surgery/Implants



Safe

 Fillings, crowns, dental posts (entirely within the tooth) associated with root canal treatment, removal of wisdom teeth

Further Information Required

- Retainers, bridges, braces
- Dental implants (are screwed into the jaw), any jaw surgery

Metallic Foreign Bodies - Orbits



- Any volunteers with a history of an orbital metallic FB should firstly have the risks associated with scanning, including blindness, explained to them
- In cases of penetrative injuries, scanning must not proceed unless there is a written radiological opinion confirming the absence of any metallic fragments
- In cases of non-penetrative intraocular metallic foreign body scanning cannot proceed unless the volunteer can state categorically that all metal fragments have been removed medically
- It is not ethical for a research volunteer to be subjected to x-rays in order to clear them for a research MRI scan. However if a written radiological opinion can be obtained on existing imaging that rules out a metallic foreign body the volunteer can be scanned.

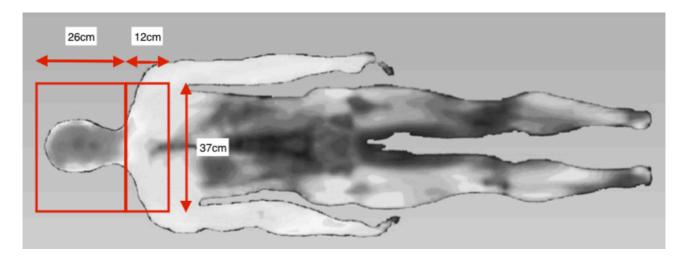
Metallic Foreign Bodies - Non-Orbits



- Unless the volunteer can state categorically that all of the metal fragments have been removed by a doctor, they will be excluded from scanning.
- It is not appropriate for a research volunteer to be subjected to x-rays in order to clear them for a research MRI scan. However if a written radiological opinion can be obtained on existing imaging that rules out a metallic foreign body the volunteer can be scanned.

Tattoos, Cosmetic Tattoos and Permanent Makeup

- Participants with tattoos that lie within the RF transmit area of the head coil will be excluded from scanning eg lip or eyebrow tattoos for head imaging
- This includes the transmit portion of the coil itself and any structures that lie within 12cm from the coil end, and within the outer 37cm diameter of the RF coil (see image below)
- Tattoos on the shoulders can fall within this area! If practical ask your participant to measure the distance from the top of their head to the start of the tattoo - anything over 35cm should be ok.
- For tattoos that may be borderline please contact <u>MRIsafety@fmrib.ox.ac.uk</u> for further guidance
- Participants with tattoos outside of the transmit coil should be warned of the rare complication of heating and to inform the radiographer or scanop immediately if they feel any heating
- Participants with new tattoos will not be scanned until 48 hours after to avoid the risk of smearing or blurring



Miscellaneous

- Artificial limbs, prosthetics eg false eyes, callipers, braces or corsets
 - Must be removed prior to entering the MR CONTROLLED AREA (scanner side of 7T console room)
 - We have MR SAFE walking sticks or an MR SAFE wheelchair if required

Medicated patches

- All medicated patches must be removed prior to scanning eg nicotine, contraceptive, pain relief, nitro
- If the patch is for a prescription medicine the participant must check with their GP that it can be removed safely for the duration of the scan
- It is recommended that the participant brings a replacement patch as it is not always possible to reapply a patch after it has been removed

Mascara and Eyeliner

- Mascara and eyeliner needs to be removed prior to the scan
- While FMRIB has makeup removing solution it is recommended that participants are warned so they can bring their own remover and makeup to reapply afterwards

• Body piercing jewellery

- All metallic body piercing jewellery must be removed for scanning
- Jewellery that is entirely plastic can remain in place
- It is recommended that participants change metal piercings to plastic piercings prior to attending for their scan (some piercings may have to be swapped by the original piercer)

Transdermal anchors

 Participants with transdermal anchors should be excluded from imaging unless there is manufacturer information regarding MR compatibility

Rings

- All rings should be removed if possible
- Participants with rings that will be within the area of the transmit coil (taken to be within 12cm of the transmit portion of the 32-channel head coil), will be excluded from scanning
- If this is not the case then the radiographer or scan operator will check it for ferromagnetic properties
- If it is not ferrous the participant will be warned regarding heating and to alert the radiographer or scanop if this happens

